Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy and investigating clinical outcomes in the intensive care unit: a randomized double-blind study

Protocol summary

Study aim
Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy

Design
En Clinical trial with 3 groups, with parallel groups, double blind, randomized, phase 3 on 105 patients. For randomization, a simple randomization method is used using a table of random numbers.

Settings and conduct
After the ethics committee's approval and obtaining the patient's consent, 105 candidates for radical cystectomy in modarres Hospital who meet the criteria as mentioned above will be included in the study. Patients are assigned to one of the 3 groups by simple randomization method. Individuals responsible for randomization from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

Participants/Inclusion and exclusion criteria
Patients who are candidates for elective radical cystectomy surgery under general anesthesia with muscle relaxation and mechanical ventilation without a history of anticoagulant therapy, blood abnormality or coagulopathy, chronic liver disease, chronic kidney disease with a serum creatinine level of > 2 mg/dL, preoperative plasma fibrinogen level of ≤150 or ≥ 400 mg/dL or history of heart infarction, deep vein thrombosis, pulmonary embolism, stroke

Intervention groups
After general anesthesia, patients are assigned to one of 3 groups that receive 2 grams of fibrinogen, or 15 mg/kg of tranexamic acid, or a combination of both as 5 mg/kg of tranexamic acid and one gram of fibrinogen intravenously.

Main outcome variables
Intraoperative hemorrhage

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230204057318N4**
Registration date: **2023-11-28, 1402/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-28, 1402/09/07**
Update count: **0**

Registration date
2023-11-28, 1402/09/07

Registrant information
Name
Alireza Shakeri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2024-11-21, 1403/09/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy and investigating clinical outcomes in the intensive care unit: a randomized double-blind study

Public title

Comparing the effect of prophylactic administration of fibrinogen and tranexamic acid in radical radical cystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for elective radical cystectomy surgery under general anesthesia with muscle relaxation and mechanical ventilation

Exclusion criteria:

Patient on anticoagulant agent Having a known blood Abnormality or coagulopathy Chronic liver disease Chronic kidney disease with a serum creatinine level of > 2 mg/dL Preoperative plasma fibrinogen level of ≤150 or ≥ 400 mg/dL History of heart infarction, deep vein thrombosis, pulmonary embolism, stroke

Age

From **40 years** old to **80 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a simple randomization method was used using a table of random numbers and through the Random generator program of the Android version. In this randomization, patients who meet the criteria for entering the study are assigned a number before anesthesia, which will represent one of the three study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the fact that the patients are unaware of the drug content, they are blinded to their group. Also, the drugs were prepared by a person outside the study group and the treatment group of patients with numbers, so the treatment group is also unaware of the colorless drug. Also, the people who perform the investigations of intraoperative bleeding and other postoperative outcomes are also blinded to the patient group. The data analyst will not know about the coding of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Yaman st., Shahid Chamran Hwy.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.415

Health conditions studied

1

Description of health condition studied

Intraoperative radical cystectomy

ICD-10 code

I97.42

ICD-10 code description

Intraoperative hemorrhage and hematoma of a circulatory system organ or structure complicating other procedure

Primary outcomes

1

Description

Intraoperative hemorrhage

Timepoint

Intraoperative

Method of measurement

Measuring of the suction bottle and bloody gauze and hemoglobin level

Secondary outcomes

1

Description
Hospitalization days
Timepoint
Postoperative period
Method of measurement
days

2

Description
ICU length of stay
Timepoint
Postoperative period
Method of measurement
Days

3

Description
Arterial blood gas
Timepoint
Intraoperative
Method of measurement
Arterial blood sampling

4

Description
Morbidity (Pneumonia, wound infection, postoperative bleeding, Deep vein thrombosis, pulmonary thromboembolism, Stroke, Myocardial infarction)
Timepoint
Postoperative
Method of measurement
Patient file

5

Description
Packed red blood cells transfusion amount
Timepoint
perioperative
Method of measurement
Milliliters

Intervention groups

1

Description
Intervention group: After general anesthesia, patients in the fibrinogen group will be administered two grams of fibrinogen intravenously dissolved in 100 ml of distilled water.
Category
Treatment - Drugs

2

Description
Intervention group: After general anesthesia, patients in the tranexamic acid group will be administered 15 mg/kg of tranexamic acid intravenously dissolved in 100 ml of distilled water.
Category
Treatment - Drugs

3

Description
Intervention group: After general anesthesia, patients in the mixed group will be administered 5 mg/kg of tranexamic acid and 1g of fibrinogen intravenously dissolved in 100 ml of distilled water.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Maede Karimian
Street address
Modarres Hospital, Saadat Abad intersection, Yadgar Imam highway
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1998734383
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pr_modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran
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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Alireza Shakeri

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available